October 8, 2021

Medtronic Vascular
Fred Boucher
Director, Regulatory Affairs
37a Cherry Hill Dr.
Danvers, Massachusetts 01923

Re: K040869
Trade/Device Name: Export Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Fred Boucher:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 1, 2004. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.10.08 10:25:04 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

Medtronic, Inc.
c/o Mr. Fred L. Boucher
Director, Regulatory Affairs
37A Cherry Hill Drive
Danvers, MA 01923

Re: K040869
Export Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: April 1, 2004
Received: April 2, 2004

Dear Mr. Boucher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bechmel

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K040869

Device Name: Export Aspiration Catheter

Indications For Use:

The Export Aspiration Catheter is indicated for:

- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040869

K040869

JUN - 1 2004

Section 7
Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. Identifying Information:

1.1.	Submitters Name:	Medtronic Vascular, Inc. 37A Cherry Hill Drive Danvers, MA 01923
1.2.	Contact Person:	Fred L. Boucher R.A.C. (978) 777-0042

2.	Classification Name:	Embolectomy Catheter (21 CFR Part 870.5150)
3.	Proprietary Name:	Export Catheter
4.	Name of Predicate Devices:	Medtronic Export Catheter (K030201) Vascular Solutions Pronto Extraction Catheter (K032763)

5. Description:

The Export Catheter is a dual lumen catheter for use with the GuardWire Temporary Occlusion and Aspiration System. The main (continuous) lumen of the catheter is the aspiration/infusion lumen while the smaller of the lumens is the guidewire lumen. The size of the wire lumen is sized so that the Export catheter may run over a 0.14-inch wire smoothly. Also, the wire lumen is designed as a single operator lumen, as such it is only present on a small section of the distal end of the catheter. The larger sized lumen is the aspiration lumen. An aspiration syringe is provided, as is an aspiration line. These are attached to the proximal end of the Export to facilitate blood and debris being evacuated from the site into the syringe.

6. Intended-Use:

The Export Catheter is designed as an aspiration catheter. The Export Catheter has substantially equivalent indications for use as the legally marketed predicate devices. The indication for use of the Export catheter are presented here.

The Export Aspiration Catheter is indicated for:

- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.

7. Technology:

The Export Catheter is manufactured in the same manner, using the same processes and materials, as the Export Catheter, a legally marketed predicate device. In addition to being technologically equivalent to the predicate devices, the Export Catheter has been subjected to performance testing and it has been determined that the Export Catheter is suitable for its intended use.